



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 174

[EPA-HQ-OPP-2014-0457; FRL-9922-53]

#### Temporary Exemption from the Requirement of a Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a temporary exemption from the requirement of a tolerance for residues of the VNT1 protein in potato when used as a plant-incorporated protectant in accordance with the terms of Experimental Use Permit (EUP) No. 8917-EUP-2. J.R. Simplot Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting the temporary tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of VNT1 protein in potato. The temporary tolerance exemption expires on December 31, 2015.

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

#### SUPPLEMENTARY INFORMATION).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0457, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [BPPDFRNotices@epa.gov](mailto:BPPDFRNotices@epa.gov).

## SUPPLEMENTARY INFORMATION:

### I. General Information

#### A. *Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

#### B. *How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 174 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

#### C. *How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0457 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0457, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## II. Background and Statutory Findings

In the **Federal Register** of October 24, 2014 (79 FR 63594) (FRL-9916-03), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 4F8251) by J.R. Simplot Company, 5369 W. Irving St., Boise, ID 83706. In the **Federal Register** of December 17, 2014 (79 FR 75107) (FRL-9918-90), EPA inadvertently reannounced the filing of this same petition. The petition requested that 40 CFR part 174 be amended by establishing a temporary exemption from the requirement of a tolerance for residues of Potato Late Blight Resistance protein VTN1 in or on potato. Those documents referenced a summary of the petition prepared by the petitioner J.R. Simplot Company, which is available in the docket, <http://www.regulations.gov>. Comments were received, and EPA's response to these comments is discussed in Unit VII.B.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...." Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider "available information concerning the cumulative effects of a particular pesticide's residues" and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines

exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

### III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability, and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

#### A. Product Characterization Overview

The gene that confers Potato Late Blight Resistance (*Rpi-vnt 1*) is found naturally in wild potato varieties. When *Rpi-vnt 1* is expressed in potato, the VNT1 protein it encodes confers broad-spectrum resistance to *Phytophthora infestans*, late blight of potato. VNT1 activates a signal transduction pathway that leads to localized plant cell death or the hypersensitive response. Death is restricted to a few plant cells and limits the growth and spread of *Phytophthora infestans* throughout the rest of the plant.

Although people have not been exposed to the VNT1 protein in potatoes (because it is currently only found in wild potato varieties), humans have been exposed to the VNT1 protein in tomatoes. In addition to conferring resistance to late blight in potato, the VNT1 protein also confers resistance to late blight in tomatoes. Both potato and tomato, which both belong to the *Solanum* genus, are affected by late blight and have developed resistance through the same VNT1 protein.

In addition, the VNT1 protein found in wild potatoes and tomatoes is similar to several other protein sequences in tomatoes. The protein in tomato species most closely related to the VNT1 protein (over 90% similarity) introduced into potato is called Tm-2 or Tm2<sup>2</sup>, which is a protein bred into tomato for resistance to the tomato mosaic virus.

#### B. Mammalian Toxicity and Allergenicity Assessment

Since the VNT1 protein is not detectable by current methodologies and attempts to isolate or produce the VNT1 protein were not successful, no toxicity testing was performed with either plant purified protein or protein produced in a surrogate organism. Rather, the Agency has reviewed a bioinformatics analysis of the allergenic and toxic potential of the VNT1 protein and on similar proteins to which humans are currently and regularly exposed through ingestion of edible plants. The Agency has identified known allergens found in potatoes and tomatoes, and the analysis shows that VNT1 protein does not have any similarity to any known allergens.

The Agency has not identified any other potential toxicity with the VNT1 protein. Although some proteins may have toxic properties, those proteins are not found in tomato or potato, and the VNT1 protein does not have any similarity to those proteins. Furthermore,

consumers have been exposed previously to the VNT1 protein in tomatoes. Also, consumers have been exposed to the very similar Tm-2 protein in tomato. Many tomato mosaic virus resistant tomato varieties are readily available and grown in the US for fresh market tomato production and are widely consumed. Since no health or toxicity issues have been raised in tomato containing the Tm-2 protein, the Agency does not expect any toxicity to be associated with the VNT1 protein in potato.

Therefore, EPA concludes that VNT 1 protein is not likely to pose any toxicity or cause any allergenicity based on the following:

1. The VNT 1 protein has been a component of the human diet from ingestion of tomatoes for a long time.
2. The VNT 1 protein is similar to other proteins to which people are regularly exposed in their diet without adverse effect.
3. The VNT 1 protein is not similar to any known allergens.

#### **IV. Aggregate Exposures**

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

The Agency has considered available information on the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances. These considerations include dietary exposure under the tolerance exemption and all other tolerances or exemptions in effect for the residues of plant-incorporated protectant, and exposure from non-occupational sources.

The Agency expects consumers to be exposed to the VNT 1 protein through potatoes containing the plant-incorporated protectant derived from the *Rpi-vnt1* gene and to other potatoes and tomatoes containing the gene naturally. Since this protein will be directly incorporated into the potato in a plant-incorporated protectant, the Agency does not expect any exposure through drinking water or through inhalation or dermal routes of exposure. The Agency also does not expect any non-occupational (i.e., other residential)

exposure to the VNT 1 protein since there are no residential uses for this plant-incorporated protectant.

## **V. Cumulative Effects from Substances with a Common Mechanism of Toxicity**

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

EPA has concluded that the VNT1 protein in potato does not have a toxic mode of action and thus does not share a common mechanism of toxicity with other substances; therefore, section 408(b)(2)(D)(v) does not apply.

## **VI. Determination of Safety for U.S. Population, Infants and Children**

FFDCA section 408(b)(2)(C) provides that, in considering the establishment of a tolerance or tolerance exemption for a pesticide chemical residue, EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. This additional margin of exposure (safety) is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

Based on the information discussed in Unit III., EPA concludes that there are no threshold effects of concern to infants, children, or adults from exposure to the VNT 1 protein. As a result, EPA concludes that no additional margin of exposure (safety) is necessary to protect infants and children and that not adding any additional margin of exposure (safety) will be safe for infants and children.

Therefore, based on the discussion in Unit III and the supporting documentation, EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to the residues of VNT 1 protein in potato when it is used as a plant-incorporated protectant. Such exposure includes all anticipated dietary exposures and all other exposures for which there is reliable information.

## **VII. Other Considerations**

### *A. Analytical Enforcement Methodology*

The Agency has determined that an analytical method is not required for enforcement purposes since the Agency is establishing a temporary exemption from the requirement of a tolerance without any numerical limitation in association with use under EUP No.: 8917-EUP-2.

#### *B. Response to Comments*

EPA received two comments relevant to this petition.

It is unclear whether one commenter, which urged “no deregulation”, had a general comment related to the Agency’s tolerance action for the VNT1 protein. EPA’s action is establishing a regulation that would exempt residues of the VNT1 protein in potato from the requirement of a tolerance; the Agency does not consider such action to be a “deregulation”. EPA continues to regulate this pesticidal active ingredient through the FFDCA and the Federal Insecticide Fungicide and Rodenticide Act (FIFRA). To the extent the commenter is arguing generally that pesticides, including plant-incorporated protectants, should be banned on agricultural crop, the comment appears to be directed at the underlying statute and not EPA’s implementation of it. However, the existing legal framework provided by section 408 of the FFDCA states that tolerances or exemptions may be set when the Agency determines that the pesticide meets the safety standard imposed by that statute.

Another commenter raised issues in regards to pollen drift, soil health, and mammalian health for plant-incorporated protectants. In this FFDCA action, the Agency has reviewed the food safety issues for this product and has concluded the product is safe for human/animal consumption. The potatoes with the VNT1 protein are safe for human consumption at levels likely to be found in these sources. The other issues raised by the commenter, pollen drift and soil health, are not relevant to this food safety determination made under FFDCA. However, EPA has considered these issues as part of its review of the EUP regulated under FIFRA.

### **VIII. Conclusion**

The Agency concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of VNT1 protein in potato. Therefore, a temporary exemption is established for residues the VNT1 protein in potato. The experimental use permit (EUP No. 8917-EUP-2) expires on December 31, 2015, so EPA is establishing an expiration for this temporary tolerance of the same date.

### **IX. Statutory and Executive Order Reviews**

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That

Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

#### **X. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).



**List of Subjects in 40 CFR Part 174**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 4, 2015.

Kimberly Nesci,

*Chief, Microbial Pesticides Branch, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 174--[AMENDED]**

1. The authority citation for part 174 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Add § 174.534 to subpart W to read as follows:

**§ 174.534 VNT1 protein in potato; temporary exemption from the requirement of a tolerance.**

Residues of VNT1 protein in potato are exempt from the requirement of a tolerance when the *Rpi-vnt1* gene that expresses the VNT1 protein is used as a plant-incorporated protectant in potato in accordance with the terms of Experimental Use Permit No. 8917-EUP-2. This temporary exemption from the requirement of a tolerance expires on December 31, 2015.

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